IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION

Master File No. 2:12-MD-02327

MDL No. 2327

JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE

THIS DOCUMENT RELATES TO:

Lauri Bell, et al. v. Ethicon, Inc., et al.,

Case No.: 2:13-cv-05389

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO LIMIT OR EXCLUDE CERTAIN CASE-SPECIFIC TESTIMONY AND OPINIONS OF BRUCE ROSENZWEIG, M.D.

Plaintiffs Lauri and Terrill Bell (hereinafter, "Plaintiffs) respectfully request the court deny Defendants' Motion to Limit or Exclude Bruce Rosenzweig, M.D. ("Defendants' Motion") for the reasons stated below.

I. INTRODUCTION

Dr. Rosenzweig's opinions have been vetted as much as any other expert's in this MDL, and in other related MDL's. This Court has consistently found him well qualified to testify on a wide variety of topics. In fact, in an order denying Defendants' motion for new trial, this Court cited extensively to Dr. Rosenzsweig's testimony as having provided sufficient support for the plaintiff's claims, in several different areas. See Huskey v. Ethicon, Inc., No. 2:12-CV-05201, 2015 WL 4944339 at **4-8 (S.D.W. Va. Aug. 19, 2015) (discussing Dr. Rosenzsweig's testimony that the TVT-O product shrinks and deforms causing a foreign body reaction; that the heavyweight Prolene mesh was not suitable for implantation in the human body; and that the warnings in the TVT-O IFU –about "transient" groin pain were insufficient).

Dr. Rosenzsweig is a pelvic floor surgeon based in Chicago, whom Ethicon itself has described as "very skilled." He is also an assistant professor of Obstetrics and Gynecology at

Rush University Medical Center. Previously, he had fellowships at the State University of New York at Syracuse and at UCLA. He started a urogynecology program at the University of Illinois, Chicago and he has performed more than one thousand surgeries in the pelvic floor, including more than 300 surgeries to address complications associated with synthetic mesh products, including those at issue in this case. Dr. Rosenzsweig has also published numerous articles and given numerous lectures on the treatments for urinary incontinence and pelvic organ prolapse. Moreover, Dr. Rosenzweig has attended Defendants' own TVT-O and Prolift seminars and has developed extensive familiarity with both products through introduction by representatives of Defendants, the IFUs for each product, hands on experience, and independent medical literature.[1]

Dr. Rosenzweig seeks to apply his extensive knowledge and experience to opine about the Ethicon TVT-O and Prolift mesh products, Ethicon's failure to warn about numerous complications associated with the mesh products, and specific causation inter alia. Dr. Rosenzweig's complete expert report is attached to Defendants' motion as **Exhibit B** and incorporated by reference as if fully set forth herein.

The Court has written, in various Daubert orders, that "Dr. Rosenzsweig has demonstrated extensive knowledge of and experience with the process of polypropylene degradation in the body," that "[a]lthough Dr. Rosenzsweig has never designed vaginal mesh devices, he has considerable familiarity with their structure and use," that "Dr. Rosenzsweig received thorough training on the implementation of sling products in pelvic repair," that "although Dr. Rosenzsweig is not a toxicologist, he stated that he regularly encounters cytoxicity in his practice, including in women who have polypropylene mesh implants," and that "Dr.

[1] *See* Rosenzweig's Expert Report, attached as Exhibit B to Defendants' motion and incorporated herein by reference (Case 2:13-cv-05389 Doc. 44-2).

Rosenzsweig has performed over a thousand pelvic floor surgical procedures, and over 200 surgeries dealing with complications related to synthetic mesh, including the removal of numerous TVT devices." *Wilkerson v. Boston Scientific Corp.,* No. 2:13-CV-04505, 2015 WL 2087048, at **5-6 (S.D.W. Va. May 5, 2015); *Huskey v. Ethicon, Inc*., 29 F.Supp 691, 707 (S.D.W. Va. 2014). As a result, this Court wrote that it "has considered Dr. Rosenzweig as a general causation expert three times in the past, and on each occasion, I have admitted his general causation testimony on the properties of polypropylene mesh." *Tyree v. Boston Scientific Corp*., 54 F.Supp. 3d 501, 565 (S.D.W. Va. 2014), *as amended* Oct. 29, 2014. Since these opinions, Dr. Rosenzsweig's qualifications, training, and experience has only grown.

Undeterred by Dr. Rosenzweig's sterling credentials and this Court's prior orders, Defendants have challenged most of his opinions in this case. Many of the challenges raise arguments already rejected by this Court. To the extent that Defendants' motion raises any new arguments, Plaintiffs contend that such mischaracterizes Dr. Rosenzweig's testimony and opinions and/or, at best, raise issues for cross-examination, not for limitations or exclusion of his scientific expert opinions.

For these reasons, Defendants' motion should be denied.

Importantly, Defendants do not contest Dr. Rosenzweig's qualifications to testify about all of the topics in his report. They could not credibly do so in the face of all of the decisions pertaining to him in this MDL already. Moreover, they do not challenge every opinion stated, including, but not limited to opinions about the product warnings. In his report, Dr. Rosenzsweig is applying his considerable experience as a pelvic surgeon who is familiar with pelvic mesh devices, including the TVT-O and Prolift, to tell the jury what information physicians and patients need when deciding whether to use these devices. All of his opinions are relevant and

probative as to whether the TVT-O and Prolift products were safe and whether they contained adequate warnings. Any alleged issues with Dr. Rosenzweig's opinions go to the weight of his testimony, not to its admissibility, and are properly contested through cross-examination.

II. LEGAL STANDARD

The Court is well aware of the standard. Nevertheless, Plaintiffs point to and incorporate by reference the standard of review for Daubert motions as articulated by Plaintiffs in their Daubert motion against Dr. Michael Woods, as articulated by the Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D.W. Va. 2014) and in all subsequent Daubert decisions rendered in this litigation, especially those pertaining to Dr. Rosenzweig and his expert opinions.

Daubert represents a "liberalization, not a tightening, of the rules controlling admission of expert testimony." *Cavallo v. Star Enterprise*, 100 F.3d 1150, 1158 (4th Cir. 1996). A witness may qualify as an expert based on "knowledge, skill, experience, training or education." Fed. R. Evid. 702. Expert testimony satisfies Rule 702 where it concerns "scientific, technical or other specialized knowledge," and where it will aid the jury in understanding or resolving a fact at issue. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). Further, "exclusion is the least favored means of rendering questionable scientific evidence ineffective." *Id.*

If a witness is suitably qualified, then the Daubert inquiry generally breaks down into a two-step analysis. The first issue is whether the proffered evidence represents "scientific knowledge," meaning that it is supported by appropriate validation. The second issue is whether the evidence would assist the jury – i.e. whether it is relevant. *United States v. Dorsey*, at 813. The relevance aspect of the inquiry is often discussed in terms of whether the expert's opinions "fit" the case. *See Daubert v. Merrill Dow Pharms.*, Inc., 509 U.S. 579, 591-92 (1993).

III. ARGUMENT

Defendants have raised six separate challenges to the testimony of Dr. Rosenzweig, many of which retrace previously rejected arguments. This brief will respond to each of the challenges.

A. DR. ROSENZSWEIG IS NOT PROHIBITED FROM RELYING UPON HIS GENERAL OPINIONS AND THE GENERAL OPINIONS OF OTHERS IN STATING HIS CASE-SPECIFIC OPINIONS

Defendants take issue with Dr. Rosenzweig's reliance on both his own general opinions and those of others in his report. However, there is nothing that prohibits this practice and Defendants cite no authority for this challenge. To the contrary, Dr. Rosenzweig is required to state the basis for his opinions and his reliance material and he did just that here. To the extent any opinions that ultimately go to the jury are redundant or duplicative of others, Plaintiffs will be mindful of such and not improperly waste the jury or court's time with unnecessarily repetitive or unhelpful opinions.

Any objections to the general opinions stated by Dr. Rosenzsweig or other of Plaintiffs' general experts, can and will be dealt with in the Court's orders as to those reports.

B. DR. ROSENZWEIG'S OPINIONS AS TO SAFER ALTERNATIVES ARE GENERAL IN NATURE AND APPROPRIATE FOR THE SPECIFIC REPORT AT ISSUE

Defendants misconstrue Dr. Rosenzsweig's reference to the Burch procedure, autologous fascia slings. In a footnote to their motion, they state that Dr. Rosenzsweig's opinions "*appear* to be case specific insofar as he intends to testify the Plaintiff would not have been injured an alternative procedure been performed." This is not the case.

Again, Plaintiffs are mindful of this Court's decisions in other cases, including, but not limited to the *Brooks v Ethicon* decision cited concerning the topic of the safety of alternative procedures. To be clear, any opinions expressed by Dr. Rosenzweig in his case specific report – who is also a general liability expert in this case - and any other general liability expert opinion

as to safer alternatives are not intended to overstep any of the Court's instructions as to these types of opinions. More specifically, any opinions stated as to safer alternative procedures are general in nature and, thus, a decision on the admissibility of such should be dealt with in the context of Defendants' general causation Daubert motions. As in *Brooks*, Plaintiffs ask that the Court decline to rule on these general causation issues raised in Defendants' specific causation motion.

As explicitly stated in his report, Dr. Rosenzweig also states that the Burch procedure, autologous fascia slings, and even the Dynamesh product are examples of what he believes would have been appropriate alternatives. As to the Dynamesh product specifically, Dr. Rosenzweig specifically states that "any design that would have utilized a lightweight, large-pore polypropylene material" would have been safer. He merely points to Dynamesh as one *example* of a product that uses such safer material that Defendants could have and should have used to make their products safer; not that the specific product (Dynamesh) is a "safer alternative design."

C. DR. ROSENZWEIG'S OPINIONS ABOUT THE ADEQUACY OF THE IFU (LABELING OPINIONS) SHOULD BE ADMITTED

Defendants' arguments as to warnings are simply repurposed arguments that have failed in the past. This Court has already permitted Dr. Rosenzweig to testify about the inadequacy of product warnings in several cases in this MDL and the Boston Scientific MDL. *See e.g. Wilkerson v. Boston Scientific Corp*., No. 2:13-CV-04505, 2015 WL 2087048, at *7-8 (S.D.W. Va. May 5, 2015); *Huskey v. Ethicon, Inc*., 29 F. Supp. 3d 691, 703-04 (S.D.W. Va. 2014)(holding that Dr. Rosenzweig was "qualified to testify generally on the adequacy of the TVT-O's product warnings and marketing materials."). Dr. Rosenzweig's opinions are based on his extensive knowledge as a pelvic floor surgeon who has performed 100s of surgeries, along with

his extensive review of the scientific literature and Defendants' internal documents. *See e.g. Huskey*, 29 F. Supp. 3d at 707; further see above and see Dr. Rosenzweig's report. Nothing has changed since these prior decisions. If anything, Dr. Rosenzweig's knowledge and expertise has only grown.

Through his clinical experience as a pelvic floor surgeon and experience as a testifying expert in these MDLs, Dr. Rosenzweig has gained expertise in labeling, Instructions for Use ("IFUs") and package inserts, as he has been responsible for thousands of risk-benefit discussions about medical devices and drugs. Similar to Ethicon's own Medical Directors Dr. Martin Weisberg and Dr. David Robinson, Dr. Rosenzweig is an expert in IFUs through performing surgery in the pelvic floor, reviewing IFUs, and counseling patients regarding IFUs, and testifying about the adequacy of such labels—including those accompanying Ethicon's pelvic mesh products.[2]

The law is clear that one does not have to be a "warnings expert" to opine about the need for stronger warnings. *See Pineda v. Ford Motor Co.*, 520 F.3d 237, 245 (3d Cir. 2008) (holding that district court abused its discretion by excluding engineer from testifying about need for stronger warnings in vehicle's service manual). And, based on his extensive experience with polypropylene mesh, Dr. Rosenzweig is far more qualified to talk about the need for stronger warnings than some experts who have been permitted to do so. *See, e.g.*, *McNeil-PPC, Inc.*, No. 07-348, 2011 WL 1673805, at **9-10 (E.D. Pa. May 4, 2011) (allowing professor in school of packaging to testify about the need for stronger warnings, even though she was not a medical

[2] *See* relevant portions of the Martin Weisberg Dep., previously produced in this MDL as Exhibit 4, at 665:15-666:1, 667:1-21 (asserting expertise in labeling based on clinical experience); David Robinson Dep., attached as Exhibit 5, at 1043:21-1044:6, 1045:17-25 (same) to the Plaintiffs' Daubert Response concerning Rosenzweig in *Lewis*.

doctor and not an expert in the disease allegedly caused by the drug). For all of these reasons, Dr. Rosenzweig is well qualified to opine about the need for stronger warnings.

D. DR. ROSENZWEIG'S DOES NOT SPECULATE ABOUT WHAT BELL'S IMPLANTER KNEW OR DID NOT KNOW PRIOR TO SURGERY.

Dr. Rosenzweig has no intention of giving improper state of mind or speculative testimony. Dr. Rosenzweig does not intend to waste the Court's time or that of any jury and Plaintiffs believe that he has proven that his testimony is relevant and helpful to the jury. See e.g. Huskey, 2015 WL 4944339, at **4-8 (discussing various aspects of Dr. Rosenzweig's testimony as having provided sufficient evidence for Plaintiffs to support their claims).

The facts here are that Dr. Pramudji was deposed AFTER Dr. Rosenzweig provided his report in this case. Dr. Rosenzweig reserved his right to amend and/or supplement as additional material, including deposition testimony, was provided. Nevertheless, what Dr. Rosenzweig can and does opine is what information was in the IFU at the time of Mrs. Bell's implant (and others prior) and what Defendants' knew internally and what was being published in the literature. Any contrary opinions by Dr. Pramudji go to her bias as a paid consultant for Defendants and a testifying expert in other cases on behalf of Defendants. Defendants' complaints as to Dr. Rosenzweig's comments about Dr. Pramudji are more appropriate for cross examination and jury consideration.

E. THE COURT HAS ALREADY ALLOWED DR. ROSENZWEIG TO TESTIFY AS TO CONTRACTION, SHRINKAGE, DEFORMATION, DEGRADATION, RIGIDITY, AND OTHER CHARACTERISTICS OF TVT-O AND PROLIFT+M ALLEGED HERE

Dr. Rosenzweig's opinions concerning the mesh characteristics are based on his extensive knowledge, training, and experience as set forth herein and in his report. Moreover, it is based on his review of the detailed medical records produced in this case, including, but not

limited to records describing the mesh as observed by Plaintiffs' treating physicians visually and physical examination and her treating physician's diagnoses. Plaintiffs' treating medical providers specifically described Plaintiff and/or the mesh as: exposed and palpable with chronic inflammation (Rosenzweig Rpt at Page 8); a knot in her right lower quadrant (Page 9); a palpable band of scar tissue; bumpy; with painful banding; *inter alia*. Based on his training, education, and experience, Dr. Rosenzweig is able to opine that the characteristics of mesh can be a cause of the specific conditions and symptoms from which Plaintiff suffered.

This Court has already rejected the assertion that Dr. Rosenzweig could not render opinions concerning the characteristics of mesh, even in the Huskey case relied upon by Defendants in their motion and in the Wilkerson case. Dr. Rosenzweig has testified that and explained in detail that he has "personally seen mesh that is broken, cracked, brittle and look different from when it came out of the package." *See Lewis Transcript*, Ex. E at 70:11-71:9; *see also* Rosenzweig Report here as Exhibit B to Def Motion. Dr. Rosenzweig has also explained in detail the problems that are caused by degradation and the other characteristics described herein, which include, but are not limited to: greater foreign body reaction, enhanced inflammatory response, and excessive scarring, which then leads to additional problems. *See* Def Ex B. These opinions are not only based on clinical observations. There are scientific studies and Defendants' own internal documents that support Dr. Rosenzweig's opinions on the clinical effects of degradation and the other characteristics described. For instance, a study by Imel, et al., concludes that "degradation causes surface cracking, mesh contraction, loss of mass, embrittlement, decreased melting temperature, foreign body reaction and reduced compliance of the material. Imel, A., et. Al, In Vivo Degradation of Polypropylene Pelvic Mesh, Biomaterials (2015) previously produced in the Mullins Daubert Reponse which entire response is adopted

and incorporated in relevant part as if fully set forth herein. For all of these reasons, the Court should again reject Defendants' criticism of Dr. Rosenzweig's opinions on degradation, particle loss and other characteristics. At the very least, this is more appropriate for cross examination.

Under *Daubert*, "most arguments about an expert's qualifications relate more to the weight to be given the expert's testimony than to its admissibility." *Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 782 (3d Cir. 1996). An expert witness simply "must possess some specialized knowledge or skill or education that is not in the possession of the jurors." *Certain Underwriters at Lloyd's, London v. Sinkovich*, 232 F.3d 200, 203 (4th Cir. 2000). Expertise can be based on "practical experience as well as academic training and credentials." *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000).

Here, Dr. Rosenzweig's qualifications to testify regarding the suitability of polypropylene mesh when implanted in the pelvic floor have been amply demonstrated. If Defendants feel that different credentials would produce "better" testimony, they are welcome to present that argument to the jury, but it is not a basis for excluding Dr. Rosenzweig's opinions. *See Holbrook*, 80 F.3d at 782 ("Who is 'best' qualified is a matter of weight upon which reasonable jurors may disagree.").

Contrary to Ethicon's suggestion, Dr. Rosenzweig does not have to be an expert in the characteristics of polymers to "possess some specialized knowledge or skill or education that is not in the possession of the jurors." *See Sinkovich*, 232 F.3d at 203. Dr. Rosenzweig is opining about the effect of the mesh in the vaginal region. Moreover, Dr. Rosenzweig has gone beyond his formidable education, training, and clinical experience to review scientific and medical literature, review depositions, review internal Ethicon documents, review Dr. Howard Jordi's study of explanted meshes, and conduct his own review of microscopic images from explanted

meshes.[3] All of this knowledge renders Dr. Rosenzweig well qualified to offer his opinions, regarding issues created by the mesh in vivo.

Dr. Rosenzweig's opinions are based upon the dangers of exposing the vaginal region to polypropylene.

F. DR. ROSENZWEIG'S PROFFERED OPINIONS ABOUT PLAINTIFFS' LONG TERM PROGONISIS ARE NOT SPECULATIVE

Dr. Rosenzweig's opinions concerning the mesh characteristics are based on his extensive knowledge, training, and experience as set forth herein and in his report. Moreover, it is based on his review of the detailed medical records produced in this case, including, but not limited to records describing the mesh as observed by Plaintiffs' treating physicians visually and physical examination and her treating physician's diagnoses. Dr. Rosenzweig's opinions concerning Plaintiffs' prognosis is based are not speculative but based on reasonable medical probability as stated in detail in his report. Any challenge is more appropriate for cross examination.

IV. CONCLUSION

For all of the foregoing reasons, the Court should deny Defendants' motion to exclude Dr. Rosenzweig from testifying as an expert at trial.

Dated: May 28, 2019

Respectfully submitted,
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[3] *See* Rosenzweig Report, Ex. 1, at 12-21.